REMARKS

Claims 1-2 and 5-11 have been examined and stand rejected. Claims 3-4 and 12-14 currently are withdrawn.

Claims 1-2 and 5-11 are rejected as indefinite. Applicant is amending claim 1 herein to correct a word processing error as suggested by the Office. Applicant requests withdrawal of this rejection.

The Office indicates that the rejection of claims 1-2, 5-6 and 9-11 as anticipated by BenMohamed has been withdrawn.

Claims 1-2, 5-6 and 9-11 are rejected as obvious over Prieur et al., WO 98/26074 (hereinafter "Prieur") in view of Livingston, et al., J. Immunol. 162:3088-3099, 1999 (hereinafter "Livingston").

Prieur teaches a fusion protein of IE1 and pp65 from HCMV, with a glutathione transferase sequence (GST-TE1-pp65). This antigenic protein is contemplated for use as a vaccine. The reference does not mention, or even hint at the concept of using the vaccine with any T helper epitope, much less fusing the antigenic protein with such a T helper epitope. Livingston relates to a hepatitis B virus experimental lipopeptide vaccine. The vaccine has a covalently attached synthetic palmitic acid which is required for activity. Therefore, Livingston teaches that fusions of hepatitis B epitopes and PADRE, when lipidated, can result in a CTL response. There is no teaching whatsoever, and not even a suggestion, that fusions without lipidation would be effective since Livingston omitted the appropriate control which might have shown what the Office claims. In fact, studies have shown that this vaccine does not work unless lipidated. The Livingston article is based upon the work of Vitiello et al., J. Clin. Invest. 95:341-349, 1995, which is provided in an Information Disclosure Statement accompanying this response. Table 1 of Vitiello shows that only lipidation succeeds in stimulating CTL activity. In the absence of the lipids, the vaccine taught by Vitiello et al. is inactive.

The present claims are directed to an unlipidated cytomegalovirus vaccine. The

inventor here has discovered that when a T helper epitope is fused to a CMV CTL epitope, the unlipidated peptide is active, a result that could not have been predicted from Livingston, which teaches that this is not the case with hepatitis B. There is nothing in either Prieur or Livingston, or their combination, that even hints that an unlipidated fusion peptide sequence could function as a vaccine. The art contains no guidance to the artisan to produce an unlipidated fusion molecule vaccine such as the present application claims. Therefore, there is no motivation, and absolutely no reason to expect that if one were to substitute CMV for the hepatitis B epitopes of Livingston in a fusion, that lipids would not be required.

Applicant submits that it is only with the hindsight that the present application supplies that an artisan would have realized that the present invention was possible, since the knowledge available at the time of filing indicated that with other viral epitopes, lipidation was needed for vaccine activity. A combination of Livingston and Prieur, modified to avoid lipidation would have been expected to fail. Thus, the results presented here would have been considered unexpected and surprising to the skilled artisan, rebutting any case of prima facie obviousness that the Office maintains.

Applicant submits that the Office cannot make out a prima facie case of obviousness, and even if the Office maintains the rejection, the unexpected results rebut any case of obviousness. Applicant therefore requests that the Office withdraw the rejection of claims 1-2, 5-6 and 9-11 as obvious.

Claims 1-2 and 5-11 are rejected as obvious over Prieur and Livingston, discussed above, in further view of Krieg et al., WO 1212972 [sic, WO 01/22972] (hereinafter "Krieg"). As the Office Action states, the claims here are directed to an unlipidated CMV vaccine which comprises a fusion peptide. Claim 7 specifies that the vaccine further comprises a DNA adjuvant. The discussion above, which explains why the combination of Prieur and Livingston does not teach or suggest the invention here, or provide guidance to make the combination and modifications required or a reasonable expectation of success, is incorporated here in its entirety. Krieg does not add any teaching or suggestion that makes up for these deficiencies since it does not

lead the artisan to avoid lipidation of the fusion peptide or to reasonably expect success for CMV where hepatitis B failed. Applicant therefore submits that the rejected claims are nonobvious.

Claim 7, the only claim which recites a DNA adjuvant, also recites features discussed above that are not taught or suggested in the art and for which there is no guidance. Applicant therefore submits that the Office cannot make out a prima facie case of obviousness here. Furthermore, the unexpected results discussed above would rebut any obviousness case the Office chooses to maintain.

Applicant requests withdrawal of this rejection for reasons analogous to those discussed above.

Applicant requests reconsideration of the present application and allowance of the claims as amended.

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